OCT 23 2008

ATTACHMENT 3

510(k) SUMMARY (Updated October 21, 2008)
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K080003

SUBMITTER
Binax, Inc., d/b/a Inverness Medical
10 Southgate Road
Scarborough, Maine 04074
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Establishment Registration Number: 1221359

CONTACT PERSON
Anne Jepson
anne.jepson@invmed.com (email)

DATE PREPARED
December 31, 2007 (revised October 21, 2008)

TRADE NAME
BinaxNOW® G6PD Test

COMMON NAME
BinaxNOW® G6PD Test, BinaxNOW® G6PD, Binax NOW® G6PD Test, Binax NOW® G6PD, NOW® G6PD Test, NOW® G6PD

CLASSIFICATION NAME
Glucose-6-Phosphate Dehydrogenase (Erythrocytic), Screening (per 21 CFR 864.7360)

PREDICATE DEVICE
Trinity Biotech Glucose-6-Phosphate Dehydrogenase (G-6-PDH) Deficiency reagent set, #K933934.

DEVICE DESCRIPTION
The BinaxNOW® G6PD test device consists of a lateral flow test strip comprised of a white sample pad and a reaction pad, which is located at the top of the strip (2 U.S. patents pending). The reaction pad contains the reagents necessary for the G6PD enzymatic reaction and the subsequent reduction of a nitro blue tetrazolium dye into its concomitant blue formazan product. The resulting color change on the strip indicates enough G6PD activity is present to presume the sample is not deficient.

To perform the test, a whole blood sample is mixed with red blood cell (RBC) lysing reagent in a sample preparation vial and then transferred to the test device sample pad. The lysed blood sample migrates up the test strip, reconstituting reagents in the reaction pad. When the sample front (or liquid migration) covers the entire reaction pad, the device is closed.

Test results are read visually. If no change in the red color of the sample front is observed at the test read time, the sample is presumed to be deficient in G6PD enzyme activity. Samples normal in G6PD activity produce a distinct color change - the red sample color changes to a brown / black color on the upper half of the reaction pad.

INTENDED USE

The BinaxNOW® G6PD (Glucose-6-Phosphate Dehydrogenase) Test is an *in vitro* enzyme chromatographic test for the qualitative detection of G6PD enzyme activity in human venous whole blood, collected in heparin or ethylenediaminetetraacetic acid (EDTA). The BinaxNOW® G6PD Test is a visual screening test used for differentiating normal from deficient G6PD activity levels in whole blood and is intended to aid in the identification of people with G6PD deficiency. Samples which generate deficient results should be assayed using a quantitative G6PD test method to verify the deficiency.

TECHNOLOGICAL CHARACTERISTICS

The BinaxNOW® G6PD Test and the predicate Trinity Biotech Glucose-6-Phosphate Dehydrogenase (G-6-PDH) Deficiency reagent set utilize different technologies. The BinaxNOW® test uses lateral flow, enzyme chromatographic technology, while the Trinity Biotech G-6-PDH Deficiency reagent set is a liquid system fluorescing "spot" assay. Both tests are qualitative tests for the visual determination of G6PD deficiency in whole blood.

PERFORMANCE SUMMARY

Clinical Sample Performance – BinaxNOW® G6PD Test Method Comparison

The performance of the BinaxNOW® test was compared to a commercially available quantitative G6PD test in a prospective study conducted in 2007-2008 in the U.S. Both heparinized and EDTA whole blood specimens were collected from 246 subjects and were evaluated on the BinaxNOW® test.

All of the samples that generated a value less than or equal to 2.0 U/gHb on the comparative method generated deficient results on the BinaxNOW G6PD test.

The percent agreement analyses and 95% confidence intervals for the BinaxNOW® G6PD test results for detection of G6PD enzyme activity deficiency, as compared to the comparative method, on both heparinized and EDTA blood samples, is provided below. For both sample types, a comparative method cut-off value of 4.2 U/gHb was used in the analysis. For all results less than or equal to 4.2 U/gHb on the comparative method, a deficient BinaxNOW result was considered a correct result. Likewise, for all comparative method results greater than 4.2 U/gHb, a normal BinaxNOW result was considered a correct result.

% AGREEMENT WITH HEPARIN SAMPLES:

		Comparative Method → Deficient	Normal
BinaxNOW Test →	Deficient	48	4
	Normal	1	190

"Deficient result" percent agreement = 48 / 49 = 98.0% (CI = 89.3 – 99.6%)
"Normal result" percent agreement = 190 / 194 = 97.9% (CI = 94.8 – 99.2%)
Overall percent agreement = 238 / 243* = 97.9% (CI = 95.3 – 99.1%)
(* 3 invalid tests)

% AGREEMENT WITH EDTA SAMPLES:

		Comparative Method → Deficient	Normal
BinaxNOW Test →	Deficient	49	5
	Normal	1	191

"Deficient result" percent agreement = 49 / 50 = 98.0% (CI = 89.5 – 99.6%)
"Normal result" percent agreement = 191 / 196 = 97.4% (CI = 94.2 – 98.9%)
Overall percent agreement = 240 / 246 = 97.6% (CI = 94.8 – 98.9%)

Additionally, BinaxNOW® test results on the heparin samples were the same as the results on the EDTA samples for 240 of the 243 subjects, whose samples generated valid results on both sample types, yielding a percent agreement of 99%.

Interfering Substances
The BinaxNOW® G6PD test was evaluated for possible interference from high levels of endogenous blood components. Whole blood samples were tested that contained bilirubin (conjugated and unconjugated), triglycerides, total cholesterol, lactic acid, lactate dehydrogenase, or glucose at concentrations above physiological levels. None of the endogenous blood components affected test performance. The presence of an elevated level of copper sulfate, which is known to inhibit G6PD enzyme activity, was also evaluated and did not affect test performance.

Blood samples with abnormally low and high hematocrit levels (17-18% and 54-65% respectively) were evaluated, and test performance was affected as described in the Limitations section of the package insert.

Reproducibility Study – Multiple Operators
A blind study of the BinaxNOW® G6PD Test was conducted at 3 separate sites using panels of blind coded specimens, which included G6PD normal and deficient samples. Participants tested each sample multiple times on 3 different days. There was 98.4% (123/125) agreement with expected test results, with no significant differences within run (replicates tested by one operator), between run (3 different days), between sites (3 sites), or between operators (6 operators).

Precision Study – Single Operator

Blood samples from two individuals were drawn into both EDTA and heparin collection tubes, and all 4 samples were tested in duplicate on the BinaxNOW test on ten successive days by a single operator. The samples collected from one individual were interpreted as normal 100% of the time. The samples collected from the other individual were interpreted as deficient 100% of the time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Binax, Inc.
Ms. Anne Jepson
10 Southgate Road
Scarborough, Maine 04074

OCT 23 2008

Re: k080003
Trade/Device Name: BinaxNOW® G6PD Test
Regulation Number: 21 CFR 864.7360
Regulation Name: Glucose-6-Phosphate Dehydrogenase (Erythrocytic), Screening
Regulatory Class: Class II
Product Code: JBF
Dated: September 19, 2008
Received: Oct 15, 2008

Dear Ms. Jepson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria Chan

Maria Chan, Ph.D
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080003

Device Name: BinaxNOW® G6PD Test

Indications for Use:

The BinaxNOW® G6PD (Glucose-6-Phosphate Dehydrogenase) Test is an *in vitro* enzyme chromatographic test for the qualitative detection of G6PD enzyme activity in human venous whole blood, collected in heparin or ethylenediaminetetraacetic acid (EDTA). The BinaxNOW® G6PD Test is a visual screening test used for differentiating normal from deficient G6PD activity levels in whole blood and is intended to aid in the identification of people with G6PD deficiency. Samples which generate deficient results should be assayed using a quantitative G6PD test method to verify the deficiency.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080003